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In The

Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, INDIVIDUALLY AND AS NEXT FRIEND OF RACHEL BROCK,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

REPLY BRIEF OF PETITIONERS

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The decision of the panel below presents an extraordinarily important question: may a federal court, in order to further its stated desire to provide drug manufacturers with greater predictability, explicitly reject the "traditional role of the jury" and effectively establish a substantive rule of federal common law requiring "statistically significant epidemiological proof" of causation in "mass toxic tort" cases? That is why six judges of the en banc court not only accused the panel of disregarding Fifth Circuit precedent, but "wonder[ed] what is left . . . of the Seventh Amendment right to trial by jury." App. 24.

Instead of attempting to explain why this extraordinarily important question is not worthy of review, Merrell pretends that it does not exist. According to Merrell, the panel below did nothing unusual – its decision conflicts with no other and presents no important federal question. As the express words of the panel and the vehement dissent of the six members of the en banc court demonstrate, however, nothing could be further from the truth.

Before addressing Merrell's legal arguments, however, we must say a few words about Merrell's primary argument – the factual assertion that forty uncontradicted epidemiological studies conclusively prove that Bendectin does not cause birth defects. To begin with, the assertion is utterly false. As the evidence in this case showed, highly qualified scientists disagree as to whether Bendectin causes birth defects. The epidemiological studies performed to date are both contradictory and inconclusive.[1]

Far more importantly, the assertion is irrelevant. The question presented by this case is not whether Bendectin causes birth defects but *who will decide* whether Bendectin

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[1] Contrary to Merrell's assertions, there are not 40 epidemiological studies of the relationship between Bendectin and birth defects. There are approximately 53, only six of which address limb reduction. Of those 53, approximately 15 establish a "statistically significant" link between Bendectin and birth defects. They were entered into evidence. The other 38 – including the six that address limb reduction – are inconclusive and only some of those were entered into evidence. Merrell's assertion that the epidemiological studies are uncontradicted and conclusive is totally unwarranted, as is its reliance on the FDA (which had no need to act once Merrell withdrew Bendectin from the market) in footnote 1 of its brief.

causes birth defects – the jury or the judge – when highly qualified experts disagree. We address Merrell's legal arguments below.

I. THIS CASE CONFLICTS EVEN WITH BENDECTIN CASES IN OTHER CIRCUITS.

Merrell first argues that this case presents no conflict because the courts are "as one in Bendectin cases" and the "non-Bendectin cases are decisively different." In fact, the panel's decision below is an unprecedented departure from uniform rulings in both Bendectin and non-Bendectin cases. What is "decisively different" is the panel's extraordinary conclusion that, even when six qualified experts testify that a particular toxic agent caused plaintiff's injuries, the jury cannot properly base a verdict on that testimony unless there is "statistically significant epidemiological proof" to support it.

Reading Merrell's brief in opposition, one would think that every plaintiff in a Bendectin case had lost and that every court to address the question had held that the question of causation was so clear that it could not go to the jury, even when supported by admissible expert testimony, because of the lack of "statistically significant epidemiological proof." In reality, however, as Merrell well knows, many Bendectin victims have succeeded in proving to juries, as the Brocks did here, that Bendectin caused their injuries. *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C.App. 1986), *on subsequent appeal*, 563 A.2d 330 (D.C.App. 1989), *cert. denied*, No. 89-961, ___ S.Ct. ___ (Feb. 20, 1990) (affirming plaintiff's verdict); *Lanzollotti v. Merrell Dow Pharmaceuticals, Inc.*, No. 82-0183

(E.D. Pa. July 9, 1986) (overruling Merrell's motion for directed verdict following mistrial due to hung jury); *Blum v. Merrell Dow Pharmaceuticals, Inc.*, 385 Pa.Super. 151, 560 A.2d 212 (1989) (ordering new trial following plaintiff's verdict because case tried to a jury of less than twelve); *Raynor v. Merrell Dow Pharmaceuticals, Inc.*, No. 83-3506 (D.D.C. 1987) (verdict returned in June of 1987, post-trial motions still pending); *Ealy v. Richardson-Merrell, Inc.*, No. 83-3504 (D.D.C. October 1, 1987) (overruling Merrell's motion for j.n.o.v. following plaintiff's verdict). In each of these cases the trial courts, having had an opportunity to view the evidence first-hand, held, as the district court did here, that there is more than sufficient evidence to support a finding in plaintiffs' favor. Indeed, in the District of Columbia, Bendectin victims have not only gotten their cases to a jury and won, but the appellate courts have fully upheld the jury's verdict, firmly ruling that the "statistically significant epidemiological proof" required by the panel below is not necessary. *Oxendine, supra*, 506 A.2d at 1110. Merrell, of course, does not mention any of these cases.

Equally important, even the cases that Merrell does mention directly conflict with the ruling of the panel below. Thus, in both *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988), *cert. denied sub nom., Hoffman v. Merrell Dow Pharmaceuticals, Inc.*, 109 S.Ct. 788 (1989) and *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149 (10th Cir. 1990), the courts upheld verdicts after the district court had necessarily ruled *that there was sufficient evidence to permit the jury to rule in plaintiffs' favor.* In *In re Bendectin Litigation*, the Sixth Circuit even expressly acknowledged that "the jury verdict following trial here

might have been for the plaintiffs instead of for the defendant." 857 F.2d at 325. Recently, federal district judges in the First, Sixth, and Tenth Circuits have reaffirmed that whether Bendectin causes birth defects is a question for the jury.[2] All of these decisions were issued after the panel's opinion in this case, and, significantly, two of them were issued by the judges who had presided over the trials in *In re Bendectin* and *Wilson*. Thus, *In re Bendectin* and *Wilson* cannot conceivably stand for the proposition that a reasonable jury could not find that Bendectin causes birth defects. As Judge Rubin stated, "A contrary finding is unjustifiable without a pronouncement in this circuit that, as a matter of law, epidemiological studies are the sole basis upon which an expert may reasonably rely when forming an opinion on a drug's teratogenicity."[3]

Similarly, *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987), and *Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989) provide no support for the decision below. In the former, the plaintiff submitted virtually no evidence in opposition to the motion for summary judgment. Consequently, a district court in the First Circuit subsequently facing the causation issue in a

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[2] *Comeau v. Richardson-Merrell, Inc.*, No. 85-0996 (D.Mass. March 1, 1990); *In re: Bendectin Products Liability Litigation*, No. 84-0963-N (E.D.Mich. January 17, 1990); *Barton v. Richardson-Merrell, Inc.*, No. 85-C-28 (D.Utah February 2, 1990); *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, No. 82-C-710-E (N.D.Okla. March 2, 1990). Copies of all unreported decisions have been docketed with the Clerk of this Court and provided to counsel for respondents.

[3] *In re: Bendectin Products Liability Litigation, supra* note 2, at 10.

Bendectin case has refused to follow *Lynch*.[4] In *Richardson*, the court held the plaintiff's evidence inadmissible under Fed.R.Evid. 703. Neither court held – indeed, except for the panel below, no court has ever held – that qualified and admissible expert testimony of causation simply cannot be credited absent "statistically significant epidemiological proof."

Attempting to explain away the panel's astounding departure from established law, Merrell argues that the ruling below is limited to Bendectin cases and that non-Bendectin cases are different. A simple reading of the opinion reveals, however, that the panel did not limit its decision to Bendectin cases; on the contrary, it perceived its ruling as a potential "solution" to the "problem" of "mass toxic torts" in general. At least one district court in the Fifth Circuit has already responded accordingly, and has ruled that the evidence presented by the plaintiff in a case involving neurological damage allegedly caused by the drug Accutane was insufficient as a matter of law to support a jury finding that the drug caused the damage.[5] Responding to the plaintiff's attempt to distinguish *Brock* as a case turning on the peculiar medical research relating to Bendectin, the court in that case observed that

> the *Brock* court cites and discusses cases involving the swine flu vaccine, a urea-formaldehyde [sic], paraquat and Agent Orange. This court is of the opinion that *Brock, supra*, is applicable to and controlling in the case before this court.[6]

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[4] *See Comeau, supra* note 2.

[5] *See Thomas v. Hoffman-La Roche, Inc.*, No. 86-19-D-D (N.D.Miss. November 14, 1989).

[6] *Thomas, supra* note 5 at 14-15.

For this reason, Merrell's attempt to distinguish *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986), *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C.Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984), and the other cases cited in our petition at 15-17, is unavailing. Merrell's essential argument is that those cases are different because there, the scientific evidence was "inconclusive" (brief of respondent at 10) and here, the scientific evidence is "thorough and conclusive." *Id.* The "conclusiveness" of the causation evidence is, of course, an argument that the jury, as well as the trial court, rejected below. As noted above, the truth is that, as even the panel below conceded, Bendectin's teratogenicity is a subject "upon which even our brightest medical minds disagree." App. 6. When that is the case, as every court before the panel below has held, the jury is to hear and resolve the dispute among the experts. Because the decision below directly and dangerously conflicts with these rulings, it requires review by this Court.

II. THE COURT OF APPEALS EXCEEDED ITS POWER TO REVIEW THE JURY'S FINDINGS OF FACT, AND ADOPTED A SUBSTANTIVE RULE OF LAW IN VIOLATION OF THE RULE OF *ERIE*.

Merrell next asserts that this case presents no important federal question because it simply involves the application of well established rules to particular facts. It is precisely because these rules are so well established, however, that this case is so important. The panel in this case was quite explicit in its unwillingness to follow them.

As Merrell notes in its brief at 12, the court below "fully understood the rules. It stated them accurately." That fact makes all the more astonishing the court's overt refusal to follow them. The court insisted that the problems posed by "mass toxic tort" cases in general required that the rules, i.e., the "traditional role of the jury," be reconsidered. Indeed, it admittedly substituted its "opinion" for that of the jury's. That is why the six en banc dissenters "wonder[ed] what is left . . . of the Seventh Amendment." App. 24.

Precisely because the panel believed that the current rules, as applied, did not provide sufficient predictability to drug manufacturers, it announced a new rule – effectively establishing a federal common law requirement of "statistically significant epidemiological proof" in "mass toxic tort" cases. Merrell does not challenge the Brocks' contention that such a requirement is unheard of in Texas tort law, but argues instead that the Brocks are complaining of the standard applied by the court of appeals for determining the sufficiency of the evidence to support the jury's findings. This response misrepresents the nature of the Brocks' complaint. The Brocks do not complain that the court of appeals improperly applied a federal standard to determine whether the Brocks' evidence presented a jury issue, but that the court developed a brand new substantive requirement for establishing a right to recover in toxic tort cases. In the panel's view, proof "by a preponderance of the evidence" is not enough – statistically significant epidemiological proof is required.[7] But

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[7] To say that the court's opinion does not establish a new substantive prerequisite to recovery, but merely advises what

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Texas courts have never intimated that such statistical proof is a prerequisite to recovery. Indeed, the idea that a plaintiff's right to recovery hinges on whether he can produce an epidemiological study that has a ninety-five percent chance of being correct, which the court of appeals required of the Brocks in this case, would be anathema to a Texas court. The panel's opinion thus directly contravenes the directives of the Tenth Amendment and of this Court in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), and must be reexamined.

CONCLUSION

The jury in this case accepted the plaintiff's proof of causation and rejected Merrell's evidence that Bendectin is not a teratogen, as have other juries throughout the country. The court of appeals, motivated by policy concerns that it was unauthorized and unqualified to evaluate, disregarded the jury's factual finding. If principles of federalism and the right to trial by jury are to mean

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proof is necessary to establish the necessary degree of likelihood, begs the question. Under the same reasoning, a federal court could adjust the state-prescribed standard of care in a strict liability case by stating that unless the plaintiff proved that the manufacturer actually knew of the hazard, plaintiff cannot sufficiently show that the product is unreasonably dangerous to comport with federal sufficiency of the evidence standards. Such legerdemain does not validly relieve the federal courts of the responsibility to judge liability under state standards.

anything in toxic tort cases, this Court should review the decision of the court of appeals in this case.

Respectfully submitted,

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